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EXAMINER

FOX, D

ART UNIT	PAPER NUMBER
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134

DATE MAILED:

03/08/90

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☒ This application has been examined      ☒ Responsive to communication filed on 12/18/89      ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s),        days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☐ Notice of References Cited by Examiner, PTO-892. 2. ☐ Notice re Patent Drawing, PTO-948.  
3. ☐ Notice of Art Cited by Applicant, PTO-1449. 4. ☐ Notice of Informal Patent Application, Form PTO-152  
5. ☐ Information on How to Effect Drawing Changes, PTO-1474. 6. ☐

## Part II SUMMARY OF ACTION

1. ☒ Claims 1-18 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-18 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☒ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other \_\_\_\_\_

Art Unit 184

The rejections of the claims under 35 USC 112 first and second paragraphs have been withdrawn, in view of Applicants' amendment filed 18 December 1989, as well as Applicants' arguments in the amendment regarding the intermediate nature of the vector of claim 10.

The text of those sections of Title 35 U. S. Code not included in this action can be found in a prior Office action.

Claims 1-15 remain rejected under 35 U.S.C. 103 as being unpatentable over Anderson taken with Guilley et al.,<sup>as</sup> stated in the last office action.

Claims 16-18 remain rejected under 35 U.S.C. 103 as being unpatentable over Anderson taken with Guilley et al. as applied to claims 1-15 are above, and further in view of Zambryski et al., as stated in the last office action.

Applicant's arguments filed 18 December 1989, insofar as they pertain to the rejections above, have been fully considered but they are not deemed to be persuasive.

Applicants urge that rejection of the claims under 35 USC 103 is improper, given the unpredictability inherent in the function of heterologous viral promoters and the lack of teaching by any of the cited references of chimeric genes comprising an isolated Ca MV promoter. With respect to the unpredictability inherent in viral promoter function, the Examiner notes that the viruses

cited by Applicants which require trans-acting proteins encoded by other portions of the viral genome for efficient promoter function do not appear to be closely related to CaMV. Furthermore, the Examiner maintains that Anderson does not teach successful promoter function of the thymidine kinase promoter in plant cells (see, e.g., column 6, lines 14-28, where recovery of kanamycin-resistant plant cells indicated the expression of the heterologous gene under the control of the viral promoter). In addition, Guilley et al. demonstrates successful function of the CaMV 35 S and 19 S promoters when small fragments of the CaMV genome are used (see, e.g., page 769, column 2; page 770). It is noted that only a reasonable expectation of success, rather than absolute predictability, is required for determinations of obviousness, as taught in In re O'Farrell, 7 USPQ 2d 1673,1681 (Fed. Cir. 1988).

With respect to the lack of suggestion to utilize isolated CaMV promoters for heterologous gene expression in plants, the Examiner maintains that one of ordinary skill in the art would try the CaMV promoters and reasonably expect success, given the teaching of heterologous gene expression in plants under the control of a viral promoter by Anderson, the teaching of the strength of the CaMV promoters by Guilley et al., and the teaching of heterologous gene expression in plants regenerated from cells transformed with a disarmed vector by Zambryski et al.

Art Unit 184

No claim is allowed.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE (3) MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO (2) MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE (3) MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX (6) MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to David Fox at telephone number 703-557-7415.

DF  
Fox/sg

3/6/90

  
CHARLES F. WARREN  
SUPERVISORY PATENT EXAMINER  
GROUP ART UNIT 124

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